IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TEXAS
WACO DIVISION

W. H. WALL FAMILY HOLDINGS, LLLP, **Plaintiff,** **v.** **VERYAN MEDICAL LIMITED,** **Defendant.**	**Jury Trial Demanded** **Civil Action No. 6:20-cv-00714**

COMPLAINT FOR PATENT INFRINGEMENT

Pursuant to the Federal Rules of Civil Procedure, W. H. Wall Family Holdings, LLLP ("WFH") files its Complaint for Patent Infringement against Defendant Veryan Medical Limited ("Defendant"), showing this Court as follows.

NATURE OF THE ACTION

1. WFH is the owner by assignment of U.S. Patent No. 6,974,475 (the "'475 Patent"). [A true and correct copy of the '475 Patent is attached hereto as Exhibit 1]. The '475 Patent is a pioneering patent in the field of medical stent technology, with a priority date of December 8, 1987, and a term ending on December 12, 2022.

2. This action arises out of Defendant's infringement of certain claims of the '475 Patent.

THE PARTIES

3. Plaintiff WFH is a limited liability limited partnership organized and existing under the laws of the state of Georgia. WFH's principal place of business is in Stone Mountain, Georgia.

4. Upon information and belief, Defendant was founded in September 2005 as the result of research regarding vessel geometry, blood flow mechanics and vascular disease performed at the Imperial College in London. Among other things, Defendant develops, manufactures and distributes medical devices utilizing the principle of biomimicry, *i.e.*, devices that imitate structures occurring naturally within the human body. Upon information and belief, Defendant is a limited company organized under the laws of the United Kingdom, with its principal place of business located at 15 City Business Centre, Brighton Rd, Horsham, West Sussex, RH13 5BB SXW. Upon information and belief, Defendant does business in the State of Texas, including in the Western District of Texas.

5. Upon information and belief, Defendant is owned by Otsuka Medical Devices Co., Ltd., a holding company wholly-owned by Otsuka Holdings Co., Ltd., a multi-national company headquartered in Tokyo, Japan and listed on the Tokyo Stock Exchange (the "TSE") under code: 4578.

JURISDICTION AND VENUE

6. This action arises under the patent laws of the United States, namely 35 U.S.C. §§ 271, 281, and 284-285, among others.

7. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a).

8. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1391(c). Defendant is a foreign entity and may be sued in any judicial district under 28 U.S.C. § 1391(c)(3).

9. Upon information and belief, Defendant is subject to this Court's specific and general personal jurisdiction pursuant to due process and/or the Texas Long Arm Statute, due at least to its substantial business in this State and judicial district, including: (A) at least part of its infringing activities alleged herein; and (B) regularly doing or soliciting business, engaging in other persistent conduct, and/or deriving substantial revenue from goods sold and services provided to Texas residents. For example, Defendant conducted its Evaluation of Safety and Effectiveness of the BioMimics 3D Stent System (MIMICS-2) with patients at Austin Heart Research in Austin, Cardiovascular Specialist of TX / North Austin Medical Center in Austin, and Mission Research Institute/Guadalupe Regional Medical Center, in New Braunfels—all within this District.

10. This Court has personal jurisdiction over Defendant, directly or through intermediaries, including its U.S.-based direct sales team, because it has committed acts within Texas giving rise to this action and/or has established minimum contacts with Texas such that personal jurisdiction over Defendant would not offend traditional notions of fair play and substantial justice.

11. Upon information and belief, Defendant has placed and continues to place devices infringing the '475 Patent into the stream of commerce via an established distribution channel with the knowledge and/or intent that those products were sold and continue to be sold in the United States, including in the state of Texas and this District.

12. Upon information and belief, Defendant has significant ties to, and presence in, the State of Texas and this District, making jurisdiction in this judicial district both proper and convenient for this action.

ATHEROSCLEROSIS AND STENT TECHNOLOGY

13. Atherosclerosis is a buildup of cholesterol and fatty deposits, i.e., plaque, that narrows or blocks blood flow within arteries. Coronary artery disease ("CAD") is a form of atherosclerosis in which plaque narrows or blocks blood flow in the arteries supplying the heart. Similarly, peripheral artery disease ("PAD") is a form of atherosclerosis in which plaque narrows or blocks blood flow in arteries not leading to heart, such as those leading to an arm or leg.

14. These blockages, or atherosclerotic lesions, are frequently treated with percutaneous transluminal intervention (PTI).

15. Initial PTI procedures included coronary angioplasty, first performed by Andreas Greuntzig in 1977.

16. During an angioplasty procedure, a specially designed catheter with a tiny balloon is carefully guided through the artery to the blockage, then inflated to widen the opening and increase blood flow within the artery. Although largely effective, angioplasty occasionally resulted in a number of adverse effects, including damage to the artery or post-operative closure of the artery.

17. Over time, doctors have recognized that these adverse effects from treating atherosclerosis with angioplasty alone may be mitigated by using stents in conjunction with angioplasty. A stent is a wire mesh tube or "scaffold" that is permanently implanted in the artery to keep the artery open and can be combined with angioplasty to treat atherosclerosis. The stent helps support the inner wall of the artery following the PTI procedure.

18. Generally speaking, there are two types of stents: (1) balloon-expandable stents and (2) self-expandable stents.

19. Balloon-expandable stents are biased in a collapsed position and the surgeon uses an angioplasty balloon to expand and set the stent within the arterial segment containing the blockage. With balloon-expandable stents, a balloon is

inflated to compress the plaque that has built up inside the artery against the artery's wall. The stent, which was carried on the deflated balloon, expands when the balloon expands, and is pushed into place in the artery. The balloon is then deflated and removed along with the catheter, leaving the stent in place.

20. Self-expandable stents are biased in an expanded position but are constrained within a delivery mechanism until placement, when the surgeon removes the constraining device allowing expansion of the stent. With self-expandable stents, the surgeon may also utilize balloon angioplasty to expand the artery prior to stent placement.

THE '475 PATENT

21. In 1981, while he was working as a visiting clinical professor at Emory Dental School, Dr. Wall became acquainted with Dr. Greuntzig, who had recently joined the Emory faculty. Dr. Wall studied the balloon angioplasty therapy pioneered by Dr. Greuntzig and concluded that arterial blockage would likely return in patients—a condition referred to as restenosis. Dr. Wall considered this issue and began working on ideas to address this problem. Initially, he tried to develop an ultrasound method to remove the blockage.

22. After experimenting with this idea, Dr. Wall concluded that this method was not a viable solution. On or about October 15, 1984, he conceived the invention of inserting a sleeve into an artery following an angioplasty procedure.

The sleeve would then effectively hold open the artery and prevent restenosis. Dr. Wall filed a disclosure document with the USPTO in December 1984, and filed patent application no. 07/129,834 (the "'834 Application") on December 8, 1987.

23. The '834 Application duly issued as the '475 Patent on December 13, 2005.

24. WFH is the owner by assignment of all rights in the '475 Patent.

25. The '475 Patent relates generally to a prosthesis that can be inserted into a bodily lumen while in a collapsed position, and then expanded in order to prevent restenosis in the lumen. WFH has the right to enforce the '475 Patent and to recover all damages available under law.

26. As an example, Claim 39 of the '475 Patent provides:

> 39. A stent for placement into a narrowed opening of a lumen of the human body and for maintaining at least a minimum opening within the lumen, said stent comprising:
>
> a radially collapsible sleeve formed in a mesh and a coating applied thereto,
>
> said sleeve defining a plurality of openings throughout the mesh to allow tissue to grow therethrough, and
>
> said mesh being biased toward either its collapsed position or its expanded position.

27. The ’475 Patent, and Dr. Wall’s invention described therein, have been the subject of numerous articles, including a 2006 article in the Wall Street Journal, entitled “Will Stent Makers Fight Dentist’s Patent Tooth and Nail?”

28. In 2008, Boston Scientific Corp. filed a well-publicized declaratory judgment action, seeking to invalidate the ’475 Patent.

29. Since 2008, press articles have discussed settlements of WFH’s claims of infringement of the ’475 Patent with a number of medical device manufacturers such as Boston Scientific, Johnson & Johnson, and Abbott Laboratories, including WFH’s settlement in 2020 with Celonova.

30. Defendant has had knowledge—or, with reasonable diligence would have had knowledge—of the ’475 Patent since at least 2016.

DEFENDANT’S BIOMIMICS STENT

31. Among other things, Defendant designs, develops, manufactures, imports, sells and offers for sale stent products, including the BioMimics 3D® vascular stent system (the “BioMimics Stent System”).

32. The BioMimics Stent System comprises a stent for placement into a narrowed opening of a lumen of the human body and for maintaining at least a minimum opening within the lumen. As described by the U.S. Food and Drug Administration (the “FDA”) in the 2018 Pre-Market Approval for the Misago Stent,

> The BioMimics 3D Vascular Stent System is indicated to improve luminal diameter in the treatment of symptomatic de novo or restenotic lesions in the native superficial femoral artery and/or proximal popliteal artery, with reference vessel diameters ranging from 4.0 - 6.0 mm and lesion lengths up to 140 mm.

[October 4, 2018, Pre-Market Approval for the BioMimics 3D Vascular Stent System, a copy of which is attached hereto as Exhibit 2, at p. 1].

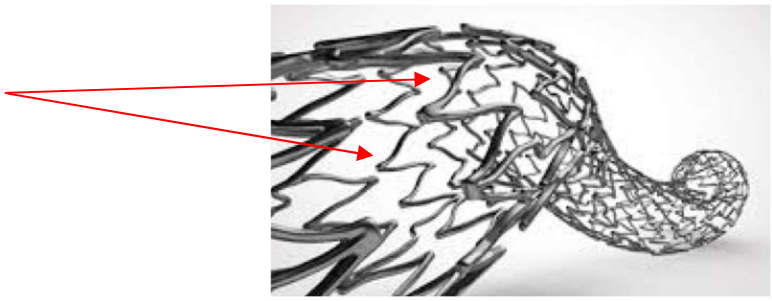
33. The BioMimics Stent System:

> [I]s comprised of two components; (i) a Nitinol stent with a three dimensional (3D) helical profile in a range of lengths and diameters and (ii) an over-the-wire stent delivery system.
>
> The BioMimics 3D stent is a peripheral self-expanding nickel-titanium alloy (Nitinol) stent with 3D helical centerline geometry. The stent is laser cut from a straight Nitinol tube and 3D helical geometry is stored in the Nitinol shape memory. Three tantalum radiopaque markers are located at both ends of the stent to increase visibility of the stent to aid in placement.

[Veryan Medical Ltd., BIOMIMICS 3D INSTRUCTIONS FOR USE (IFU003 Issue 09) (the "BioMimics IFUs"), p. 3, a true and correct copy of which is attached hereto as Exhibit 3].

34. The nitinol stent in the BioMimics Stent System comprises a radially collapsible sleeve formed in a mesh with, upon information and belief, a coating applied thereto through passivation, such as through oxidation or electropolishing.

35. The nitinol stent in the BioMimics Stent System further comprises a sleeve defining a plurality of openings throughout the mesh to allow tissue to grow therethrough, as shown by the red arrows below.



36. The BioMimics IFUs further explain that a delivery catheter is used to position the nitinol stent in a lumen. [Ex. 3, pp. 6-8]. Once properly positioned, the nitinol stent in the BioMimics Stent System is expanded through removal of its covering sheath. [Ex. 3, p. 9-10]. Once fully expanded, the deployment of the stent is completed by removal of the delivery catheter. [Ex. 3, p. 10].

37. The nitinol stent in the BioMimics Stent System thus further comprises a mesh that is biased towards its open position but constrained by an outer sheath, removed after placement by the surgeon.

38. WFH has satisfied all statutory obligations required to collect pre-filing damages for the full period allowed by law for infringement of the '475 Patent.

39. All other conditions precedent to the assertion of the claims herein have been satisfied or waived.

COUNT I
DIRECT INFRINGEMENT—'475 PATENT

40. WFH incorporates by reference as if fully set forth herein its averments in Paragraphs 1-39, above.

41. As set forth above, the BioMimics Stent System comprises, literally or through the doctrine of equivalents, each limitation of at least Claim 39 of the '475 Patent.

42. Defendant has imported, sold for importation, sold and offered for sale the BioMimics Stent System within the U.S. since at least 2018, in violation of 35 U.S.C. §271, *et seq.*

43. On information and belief, including the allegations above showing knowledge and intent, despite having knowledge of the '475 patent and knowledge that it is directly infringing one or more claims of the '475 patent, Defendant has nevertheless continued its infringing conduct and disregarded an objectively high likelihood of infringement. Defendant's infringing activities relative to the '475 patent have been, and continue to be, willful, wanton, malicious, in bad-faith, deliberate, consciously wrongful, flagrant, characteristic of a pirate, and an egregious case of misconduct beyond typical.

44. WFH has been, and continues to be, damaged by Defendant's infringement of the '475 Patent, in an amount not less than a reasonable royalty, together with interests and costs as fixed by this Court pursuant to 35 U.S.C. §284.

COUNT II
INDIRECT INFRINGEMENT—'475 PATENT

45. WFH incorporates by reference as if fully set forth herein its averments in Paragraphs 1-39, above.

46. Upon information and belief, Defendant also has indirectly infringed the '475 Patent by inducing others, including members of its US-based direct sales force, to infringe directly the '475 Patent.

47. Upon information and belief, Defendant has taken affirmative actions, directly or through its wholly-owned U.S. subsidiary, with the specific intent to cause its wholly-owned U.S. subsidiary and customers within the U.S. to make, use, offer to sell, sell or import into the United States the Biomimics Stent System in a manner that infringes at least Claim 39 of the '475 Patent.

48. Upon information and belief, such affirmative actions included, among other things, advising or directing customers and end-users to use the Biomimics Stent System in an infringing manner; advertising and promoting the use of the Misago Stent in an infringing manner; and/or distributing instructions that guide users to use the Misago Stent in an infringing manner.

49. Upon information and belief, Defendant has taken these steps, which constitute induced infringement, with the knowledge of the '475 Patent and that such steps induced infringement of the '475 Patent, or with willful blindness of the same.

50. Upon information and belief, including the allegations above showing knowledge and intent, despite having knowledge of the '475 patent and knowledge that it is indirectly infringing one or more claims of the '475 patent, Defendant has nevertheless continued its infringing conduct and disregarded an objectively high likelihood of infringement. Defendant's infringing activities relative to the '475 patent have been, and continue to be, willful, wanton, malicious, in bad-faith, deliberate, consciously wrongful, flagrant, characteristic of a pirate, and an egregious case of misconduct beyond typical.

INJUNCTIVE RELIEF

51. WFH seeks preliminary and permanent injunctions as a result of Defendant's infringement of the '475 Patent. WFH is likely to succeed in showing that Defendant infringes the '475 Patent. Because of that infringement, WFH has suffered an irreparable injury, and the remedies available at law, such as monetary damages, are inadequate to compensate for that injury. For example, if WFH must enforce a judgment against Defendant in the United Kingdom, Plaintiff will face a challenging burden in persuading a United Kingdom court to enforce a judgment from a U.S. court, potentially preventing WFH from obtaining any monetary damages from Defendant. Considering the balance of hardships between WFH and Defendant, a remedy in equity is warranted; and the public interest would not be disserved by a permanent or preliminary injunction.

CONCLUSION

52. WFH is entitled to recover from Defendant the damages sustained by WFH as a result of Defendant's wrongful acts in an amount subject to proof at trial, which, by law, cannot be less than a reasonable royalty, together with interest and costs as fixed by this Court.

53. WFH has incurred and will incur attorneys' fees, costs, and expenses in the prosecution of this action. The circumstances of this dispute may give rise to an exceptional case within the meaning of 35 U.S.C. § 285, and WFH is entitled to recover its reasonable and necessary attorneys' fees, costs, and expenses.

JURY DEMAND

54. WFH hereby requests a trial by jury pursuant to Rule 38 of the Federal Rules of Civil Procedure.

PRAYER FOR RELIEF

55. WFH respectfully requests that the Court find in its favor and against Defendant, entering a judgment in favor of WFH and granting the following relief:

a) Finding that Defendant has infringed the '475 Patent as alleged herein, directly and/or indirectly by way of inducing infringement of such patent;

b) Requiring an accounting of all damages sustained by WFH as a result of the acts of infringement by Defendant;

c) A preliminary and permanent injunction against Defendant, its subsidiaries, or anyone acting on its behalf from making, using, selling, offering to sell, or importing any products that infringe the '475 Patent and any other injunctive relief the Court deems just and equitable;

d) Awarding to WFH damages under 35 U.S.C. §284, including not less than a reasonable royalty and up to treble damages;

e) Requiring Defendant to pay WFH pre-judgment and post-judgment interest on the damages awarded;

f) Awarding to WFH the statutory costs of this action;

g) Finding this to be an exceptional case and requiring Defendant to pay to WFH its attorneys' fees and non-statutory costs incurred in this action under 35 U.S.C. §285; and

h) Awarding WFH such other and further relief as this Court deems just and appropriate, premises considered.

This 4th day of August, 2020

Respectfully submitted,

LOCKE LORD LLP

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